

Express Mail Label No: EL 926059816 US
Date of Deposit: February 24, 2004

DOCKET NO: P0453.70113US03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Foss, et al.
Serial No: Not yet assigned
Confirmation No: Not yet assigned
Filed: February 12, 2004
For: ORAL USE OF METHYLNALTREXONE AND RELATED
COMPOUNDS TO INDUCE LAXATION IN CHRONIC
OPIOID USERS
Examiner: Not yet assigned
Art Unit: Not yet assigned

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants request consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement is being filed along with a continuation application.

PART II: Information Cited

Applicants hereby make of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicants hereby makes the following additional information of record in the above-identified application.

The following co-pending applications that may contain subject matter related to this application are enclosed unless the earlier application is identified herein and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application:

Serial No.	Filing Date	Inventor(s)	Docket No.
Not yet known	February 24, 2004	Foss et al.	P0453.70113US04
Not yet known	February 12, 2004	Foss et al.	P0453.70113US02
Not yet known	February 12, 2004	Foss et al.	P0453.70113US01
10/163,482*	June 5, 2002	Moss et al.	P0453.70109US00
10/278,630*	October 23, 2002	Foss et al.	P0453.70110.US00
10/358,560*	February 4, 2003	Foss et al.	P0453.70114US00
60/461,611*	April 8, 2003	Sanghvi et al.	P0453.70115US00
60/461,608*	April 8, 2003	Boyd et al.	P0453.70112US00
60/461,585*	April 8, 2003	Sanghvi et al.	P0453.70116US00

*A copy of this application is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 09/862,169, filed May 21, 2002, and prior application, Serial No. 10/278,630, filed October 23, 2002, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

Serial No.: not yet known

- 3 -

Art Unit: not yet known

By submitting this Information Disclosure Statement, Applicants make no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by Applicants, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Foss, et al., *Applicant*

By: Edward R. Gates
Edward R. Gates
Reg. No. 31,616
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

Docket No. P0453.70113US03
Date: February 24, 2004
x02/24/04

FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: Not yet known		ATTY. DOCKET NO.: P0453.70113US03	
				FILING DATE: February 24, 2004		CONFIRMATION NO.:	
				APPLICANT: Foss, et al.			
				GROUP ART UNIT: Not yet known		EXAMINER: Not yet known	
Sheet	1	of	4				

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	*A1	2001/0018413	A1	Crain, <i>et al.</i>	08-30-2001
	*A2	2002/0028825	A1	Foss, <i>et al.</i>	03-07-2002c
	*A3	2001/0033865	A1	Oshlack, <i>et al.</i>	10-25-2001
	*A4	2001/0036476	A1	Oshlack, <i>et al.</i>	11-01-2001
	*A5	2001/0047005	A1	Farrar, <i>et al.</i>	11-29-2001
	*A6	4,176,186		Goldberg, <i>et al.</i>	11-27-1979
	*A7	4,719,215		Goldberg	01-12-1988
	*A8	4,861,781		Goldberg	08-29-1989
	*A9	4,987,136		Kreek, <i>et al.</i>	01-22-1991
	*A10	5,102,887		Goldberg	04-07-1992
	*A11	5,270,328		Cantrell, <i>et al.</i>	12-14-1993
	*A12	5,472,943		Crain, <i>et al.</i>	12-05-1995
	*A13	5,512,578		Crain, <i>et al.</i>	04-30-1996
	*A14	5,767,125		Crain, <i>et al.</i>	06-16-1998
	*A15	5,811,451		Minoia, <i>et al.</i>	09-22-1998
	*A16	5,866,164		Kuczynski, <i>et al.</i>	02-02-1999
	*A17	5,958,452		Oshlack, <i>et al.</i>	09-28-1999
	*A18	5,972,954		Foss, <i>et al.</i>	10-26-1999
	*A19	6,096,756		Crain, <i>et al.</i>	08-01-2000
	*A20	6,194,382	B1	Crain, <i>et al.</i>	02-27-2001
	*A21	6,261,599	B1	Oshlack, <i>et al.</i>	07-17-2001
	*A22	6,274,591	B1	Foss, <i>et al.</i>	08-14-2001
	*A23	6,395,705	B2	Crain, <i>et al.</i>	05-28-2002
	*A24	6,419,959	B1	Walter, <i>et al.</i>	07-16-2002
	*A25	6,451,806	B2	Farrar	09-17-2002
	*A26	6,559,158	B1	Foss, <i>et al.</i>	05-06-2003
	*A27	6,608,075	B1	Foss, <i>et al.</i>	08-19-2003
	*A28	RE36,547		Crain, <i>et al.</i>	02-01-2000
	*A29	2002/0188005	A1	Farrar, <i>et al.</i>	12-12-2002

FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: Not yet known		ATTY. DOCKET NO.: P0453.70113US03	
				FILING DATE: February 24, 2004		CONFIRMATION NO.: Not yet known	
				APPLICANT: Foss, et al.			
				GROUP ART UNIT: Not yet known		EXAMINER: Not yet known	
Sheet	2	of	4				

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	*B1	AU	610,561		Shelley	08-17-1988	
	*B2	CA	1,315,689		The University of Chicago	04-06-1993	
	*B3	EP	0278821	A1	Shelly (Abstract)	08-17-1988	
	*B4	EP	0352361	A1	The Rockefeller University	01-31-1990	
	*B5	EP	278,821	A1	Marc Yves Shelly (Derwent Abstract)	08-17-1988	
	*B6	EP	306,575	B1	The Univ. of Chicago	03-15-1989	
	*B7	EP	352,361	A1	The Rockefeller University	01-31-1990	
	*B8	EP	760,661	B1	Minoia, <i>et al.</i>	12-30-1998	
	*B9	JP	2,625,457	B2	Goldberg (Derwent Abstract)	07-02-1997	
	*B10	NZ	222,911		The Univ. of Chicago	12-14-1987	
	*B11	WO	83/03197	A1	The Rockefeller University	09-29-1983	
	*B12	WO	88/05297	A1	Shelly	07-28-1988	
	*B13	WO	95/31985	A2	Minoia, <i>et al.</i>	11-30-1995	
	*B14	WO	97/33566		Alza Corp.	09-18-1997	
	*B15	WO	98/25613		Klinge Pharma GmbH	06-18-1998	yes
	*B16	WO	01/13909	A2	Critical Care Pharm.	03-01-2001	
	*B17	WO	01/37785	A2	Adolor Corp.	05-31-2001	
	*B18	WO	01/41705	A2	Adolor Corp.	06-14-2001	
	*B19	WO	01/42207	A2	Adolor Corp.	06-14-2001	
	*B20	WO	01/85257	A2	Pain Therapeutics, Inc..	11-15-2001	
	*B21	WO	02/060870	A2	Adolor Corp.	08-08-2002	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	*C1	AKINBAMI, <i>et al.</i> , <i>Neuroendocrinology</i> , (1994), 59(4), 343-348	
	*C2	AMIN, <i>et al.</i> , <i>Anesth. Analg.</i> (1994), 78(4), 701-5	
	*C3	AMIR, <i>Brain Res.</i> (1984) 297:187-90.	
	*C4	AMIR, <i>et al.</i> , <i>Arch. Toxicol. Suppl.</i> , (1983), 6, 261-5	
	*C5	ARGENTIERI, <i>et al.</i> , <i>Brain Res.</i> (1983), 277(2), 377-9	
	*C6	BARATTI, <i>et al.</i> , <i>Methods Find. Exp. Clin. Pharmacol.</i> , (1990), 12(7), 451-6	
	*C7	BEDINGFIELD, <i>et al.</i> , <i>Alcohol</i> 15 (1): (1998), p51-54	
	*C8	BIANCHETTI, <i>et al.</i> , <i>Life Sciences</i> (1983) 33(1), 415-18	
	*C9	BIANCHI, <i>et al.</i> , <i>Life Sci.</i> , (1982), 30(22), 1875-83	
	*C10	BLANK, <i>et al.</i> , <i>Life Sciences</i> . (1986), 39(17), 1493-9	
	*C11	BROWN, <i>et al.</i> , <i>Brain Res.</i> , (1981), 221(2), 432-6	
	*C12	BROWN, <i>et al.</i> , <i>Neuropharmacology</i> (1983), 3A (22), 317-21	
	*C13	CALCAGNETTI, <i>Pharmacol Biochem Behav</i> 1987 Jul;27(3):529-31 (Abstract only)	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: Not yet known		ATTY. DOCKET NO.: P0453.70113US03	
				FILING DATE: February 24, 2004		CONFIRMATION NO.: Not yet known	
				APPLICANT: Foss, et al.			
				GROUP ART UNIT: Not yet known		EXAMINER: Not yet known	
Sheet	3	of	4				

*C14	CHANG, et al., <i>J. Pharmacol. Exp. Ther.</i> (1984), 228(2), 364-9		
*C15	CULPEPPER, et al., <i>Clinical Trials and Therapeutics</i> (1992) 52, 90-95		
*C16	EISENBERG, <i>Life Sciences</i> , (1984), 34(12), 1185-91		
*C18	FERNANDEZ-TOME, et al., <i>Pharmacol. Biochem. & Behavior</i> (1988) 29, 387-392		
*C19	FOSS, <i>Am. Journal of Surgery</i> (2001) 182, 195-265		
*C20	FOSS, et al., <i>Anesthesiology</i> , (1995), 83(3A), p. A361		
*C21	FOSS, et al., <i>Cancer Chemother. Pharmacol.</i> (1998), 42(4), 287-291		
*C22	FOSS, et al., <i>J. Clin. Pharmacol.</i> , (1997), 37(1) 25-30		
*C23	FOSS, et al., <i>J. Clin. Pharmacol.</i> (1993), 33(8), 747-51		
*C24	FOSS, et al., <i>Life Sciences</i> 59(15), (1996), p. PL235-PL238		
*C25	FRANCE, et al., <i>Neuropharmacology</i> (1987), 26(6), 541-8		
*C26	FRANCE, et al., <i>Pharmacol. Biochem. & Behavior</i> (1985) 23, 731-736		
*C27	FRIEDMAN, et al., <i>Ann. Pharmacother.</i> , (2001), 35(1) 85-91		
*C28	GMEREK, et al., <i>J. Pharmacol. Exp. Ther.</i> (1986), 236(1), 8-13		
*C29	HEIN, et al., <i>J. Pharmacol. and Exper. Therapeutics</i> (1981), 218(1), 7-15		
*C30	JALOWIEC, et al., <i>Pharmacol. Biochem. & Behav.</i> , (1989), 33(3), 697-700		
*C31	JANCOVIC and RADULOVIC., <i>Immunopharmacology</i> (1994), 28, 105-112		
*C32	KIM, et al., <i>Chromatographia</i> , (1989), 28(7-8), 359-63		
*C33	KOBLISH, et al., <i>Society for Neuroscience Abstracts</i> , (2001)27 (2), 2407		
*C34	KOBYLECKI, et al., <i>Journal of Medicinal Chemistry</i> (1982), 25 (11) 1278-80		
*C35	KOCZKA, et al., <i>Acta Chimica Academica Scien. Hung.</i> (1967) 51(4), 393-02		
*C36	KOOB, et al., <i>J. Pharmacol. Exp. Ther.</i> (1984), 229(2), 481-6		
*C37	KOTAKE, et al., <i>Xenobiotica</i> , 1989, 19(11), 1247-54		
*C38	LEANDER, et al., <i>J. Pharmacol. Exp. Ther.</i> (1983), 224(1), 89-94		
*C39	LITTLE, et al., <i>Society for Neuroscience Abstracts</i> , 27 (2); 2001, p. 2407		
*C40	LYDON, et al., <i>European Journal of Anesthesiology</i> , 18 (Supplement 21), p. 92, 2001 (Abstract)		
*C41	LYSLE, et al., <i>Brain, Behavior and Immun.</i> (1992) 6, 179-188		
*C42	MAGNAN et al., <i>Naunyn Schmiedeberg's Arch Pharmacol.</i> (1982) 319(3), 197-205		
*C43	MANARA, et al., <i>Adv. Endog. Exog. Opioids, Poroc. Int. Narc. Res. Conf.</i> , 12th (1981), 402-4		
*C44	MANARA, et al., <i>Ann. Rev. Pharmacol. Toxicol.</i> (1985) 25, 249-73		
*C45	MICKLEY, et al., <i>Physiology & Behavior</i> , 1985, 35(2), p. 249-53		
*C46	MISRA, et al., <i>J. Pharm. Pharmacol.</i> (1987), 39(3), 225-7		
*C47	MOERMAN, et al., <i>Acta Anesthologica Belgica</i> (1995), 3-4 (46) p. 127-32		
*C48	MOSS, et al., <i>N. Engl. J. Med.</i> , (2002) 346 (6), 455		
*C49	MUCHA, <i>Brain Research</i> (1987) 418, 214-220		
*C50	MUCHA, <i>Life Sci.</i> (1989), 45, p. 671-678		
*C51	MURPHY, et al., <i>Anesthesiology</i> (1999) 91 (3A), A349, (Abstract)		
*C52	MURPHY, et al., <i>Anesthesiology</i> , (1997), 87(4), 765-770		
*C53	MURPHY, et al., <i>Br. J. Anaesth.</i> (2001), 86(1) 120-122		
*C54	MURPHY, et al., <i>J. Cardiovasc. Pharmacol.</i> , 1999, 33(1) 122-125		
*C55	NARANJO, et al., <i>Life Sciences</i> (1986) 38(21) p. 1923-30		
*C56	NELSON, <i>Dissertation Abstracts International</i> , (62/03-B), p. 1635 (Abstract)		
*C57	ODIO, et al., <i>Pharmacology Biochemistry & Behavior</i> , (1990), 35(4) 963-9		
*C58	Oncology (1996) 10(12):1880. (No authors listed)		
*C59	OSINSKI, et al., <i>J. Chromatogr. B. Analyt. Technol. Biomed. Life Sci.</i> (2002) 780(2), 251-259		
*C60	PAPPAGALLO, <i>Am. Journal of Surgery</i> (2001) (Supp. to 11/01) 182, 11S-18S		

FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: Not yet known		ATTY. DOCKET NO.: P0453.70113US03	
				FILING DATE: February 24, 2004		CONFIRMATION NO.: Not yet known	
				APPLICANT: Foss, et al.			
				GROUP ART UNIT: Not yet known		EXAMINER: Not yet known	
Sheet	4	of	4				
	*C61	POWELL, et al., <i>J. Pharmacol. & Exp. Therapeutics</i> (2002) 300(2), 588-596					
	*C62	QUOCK, et al., <i>J. Bioelectr.</i> (1986), 5(1), 35-46					
	*C63	QUOCK, et al., <i>Life Sciences</i> , (1985), 37(9), 819-26					
	*C64	QUOCK, et al., <i>Prog. Neuro. Psychopharmacol. Biol. Psychiatry</i> (1985), 9(3), 239-43					
	*C65	RAMABADRAN, <i>Life Sciences</i> , 1982, 31(12-13), 1253-6					
	*C66	ROBINSON, et al., <i>The Lancet</i> (1991) 338, 581-582					
	*C67	RUSSELL, et al., <i>Eur. J. Pharmacol.</i> (1982), 78(3), 255-61					
	*C68	SCHAEFER, et al., <i>Pharmacol. Biochem. Behav.</i> (1985), 23(5), 797-802					
	*C69	SCHMIDHAMMER, et al., <i>Helv. Chim. Acta</i> (1994), Vol. 77, No. 6, p. 1585-9					
	*C70	SCHMIDHAMMER, et al., <i>Helv. Chim. Acta.</i> (1993) No. 1, p. 476-80					
	*C71	SCHOLZ, 2000, 63 (6) p. 103					
	*C72	SCHREIER, et al., <i>Proc. West. Pharmacol. Soc.</i> (1982), 25, 151-4					
	*C73	SOLVASON, et al., <i>Brain, Behav., Immun.</i> (1989), 3(3), 247-262					
	*C74	SWAN, et al., <i>AIDS Research</i> , NIDA Notes, (1995), 10(3), 1-6					
	*C75	SYKES, <i>The Lancet</i> (1991), 337, 1475					
	*C76	THOMPSON, et al., <i>Brain Res.</i> (1996) 743, 184-201					
	*C77	UKAI, et al., <i>Psychopharmacology</i> (1987), 91(3), 279-84					
	*C78	VALENTINO, et al., <i>J. Pharmacol. Exp. Ther.</i> , (1981), 217(3), 652-9					
	*C79	VALENTINO, et al., <i>Life Sciences.</i> , (1983), 32(25), 2887-96					
	*C80	WALKER, et al., <i>Psychopharmacology</i> (1991), 104(2), p. 164-6					
	*C81	WARREN et al., <i>J. Pharmacol. Exp. Ther.</i> (1985), 235(2), p. 412-17					
	*C82	WILLETTE, et al., <i>Res. Commun. Subst. Abuse</i> (1983), 4(4), 325-37					
	*C83	YUAN et al., <i>Drug Dev. Res.</i> (2000) 50(2), 133-141					
	*C84	YUAN et al., <i>Neuropharmacology</i> (March 1999), 38(3) 425-432					
	*C85	YUAN, et al., <i>Anesthesiology</i> , Sept. (1995), 83 (3A), p A358 (Abstract)					
	*C86	YUAN, et al., <i>Anesthesiology</i> , Sept. (1995), 83 (3A), p A360 (Abstract)					
	*C87	YUAN, et al., <i>Anesthesiology</i> , Sept. (1999), 91 (3A) p. A349 (Abstract)					
	*C88	YUAN, et al., <i>Anesthesiology</i> , Sept. (1999), 91 (3A) p. A973 (Abstract)					
	*C89	YUAN, et al., <i>Clin. Pharmacol. Ther.</i> (2000), 67(4) 398-404					
	*C90	YUAN, et al., <i>Clin. Pharmacol. Ther.</i> (1997), 61(4), 467-475					
	*C91	YUAN, et al., <i>Clin. Pharmacol., Ther.</i> , (1996), 59(4), 469-475					
	*C92	YUAN, et al., <i>Clinical Pharmacology & Therapeutics</i> (1995) 57(2), p. 138					
	*C93	YUAN, et al., <i>Drug Alcohol Depend.</i> (1998), 52(2), 161-165					
	*C94	YUAN, et al., <i>European Journal of Pharmacology</i> (1995), 276 p. 107-111					
	*C95	YUAN, et al., <i>J. Pharmacol. Exp. Ther.</i> (US)300 (1), 2002, pp. 118-123					
	*C96	YUAN, et al., <i>JAMA</i> 284, No. 11, (2000), p 1383-1384					
	*C97	YUAN, et al., <i>JAMA</i> , (2000), 283 (3), 367-372					
	*C98	YUAN, et al., <i>Pain</i> (1999) 83, 631-635					
EXAMINER				DATE CONSIDERED			

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 10/358,560, filed February 4, 2003, and prior application, Serial No. 10/278,630, filed October 23, 2002, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]